

## Nuclear Regulatory Commission

## § 32.1

- 32.21 Radioactive drug: Manufacture, preparation, or transfer for commercial distribution of capsules containing carbon-14 urea each for "in vivo" diagnostic use for humans to persons exempt from licensing; Requirements for a license.
- 32.21a Same: Conditions of license.
- 32.22 Self-luminous products containing tritium, krypton-85 or promethium-147: Requirements for license to manufacture, process, produce, or initially transfer.
- 32.23 Same: Safety criteria.
- 32.24 Same: Table of organ doses.
- 32.25 Conditions of licenses issued under § 32.22: Quality control, labeling, and reports of transfer.
- 32.26 Gas and aerosol detectors containing byproduct material: Requirements for license to manufacture, process, produce, or initially transfer.
- 32.27 Same: Safety criteria.
- 32.28 Same: Table of organ doses.
- 32.29 Conditions of licenses issued under § 32.26: Quality control, labeling, and reports of transfer.
- 32.40 Schedule A—Prototype tests for automobile lock illuminators.

### Subpart B—Generally Licensed Items

- 32.51 Byproduct material contained in devices for use under § 31.5; requirements for license to manufacture or initially transfer.
- 32.51a Same: Conditions of licenses.
- 32.52 Same: Material transfer reports and records.
- 32.53 Luminous safety devices for use in aircraft: Requirements for license to manufacture, assemble, repair or initially transfer.
- 32.54 Same: Labeling of devices.
- 32.55 Same: Quality assurance; prohibition of transfer.
- 32.56 Same: Material transfer reports.
- 32.57 Calibration or reference sources containing americium-241: Requirements for license to manufacture or initially transfer.
- 32.58 Same: Labeling of devices.
- 32.59 Same: Leak testing of each source.
- 32.60 [Reserved]
- 32.61 Ice detection devices containing strontium-90; requirements for license to manufacture or initially transfer.
- 32.62 Same: Quality assurance; prohibition of transfer.
- 32.71 Manufacture and distribution of byproduct material for certain in vitro clinical or laboratory testing under general license.
- 32.72 Manufacture, preparation, or transfer for commercial distribution of radioactive drugs containing byproduct material for medical use under part 35.

- 32.74 Manufacture and distribution of sources or devices containing byproduct material for medical use.
- 32.101 Schedule B—prototype tests for luminous safety devices for use in aircraft.
- 32.102 Schedule C—prototype tests for calibration or reference sources containing americium-241.
- 32.103 Schedule D—prototype tests for ice detection devices containing strontium 90.

### Subpart C—Quality Control Sampling Procedures

- 32.110 Acceptance sampling procedures under certain specific licenses.

### Subpart D—Specifically Licensed Items

- 32.210 Registration of product information.

### Subpart E—Violations

- 32.301 Violations.
- 32.303 Criminal penalties.

AUTHORITY: Secs. 81, 161, 182, 183, 68 Stat. 935, 948, 953, 954, as amended (42 U.S.C. 2111, 2201, 2232, 2233); sec. 201, 88 Stat. 1242, as amended (42 U.S.C. 5841); sec. 1704, 112 Stat. 2750 (44 U.S.C. 3504 note).

SOURCE: 30 FR 8192, June 26, 1965, unless otherwise noted.

### § 32.1 Purpose and scope.

(a) This part prescribes requirements for the issuance of specific licenses to persons who manufacture or initially transfer items containing byproduct material for sale or distribution to:

(1) Persons exempted from the licensing requirements of part 30 of this chapter, or

(2) Persons generally licensed under part 31 or 35 of this chapter.

This part also prescribes certain regulations governing holders of these licenses. In addition, this part prescribes requirements for the issuance of specific licenses to persons who introduce byproduct material into a product or material owned by or in the possession of the licensee or another and regulations governing holders of such licenses. Further, this part describes procedures and prescribes requirements for the issuance of certificates of registration (covering radiation safety information about a product) to manufacturers or initial transferors of sealed source or devices containing sealed sources which are to be used by

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persons specifically licensed under part 30 of this chapter or equivalent regulations of an Agreement State.

(b) The provisions and requirements of this part are in addition to, and not in substitution for, other requirements of this chapter. In particular, the provisions of part 30 of this chapter apply to applications, licenses and certificates of registration subject to this part.

[30 FR 8192, June 26, 1965, as amended at 52 FR 27786, July 24, 1987; 63 FR 1896, Jan. 13, 1998]

### § 32.2 Definitions.

As used in this part:

(a) *Dose commitment* means the total radiation dose to a part of the body that will result from retention in the body of radioactive material. For purposes of estimating the dose commitment, it is assumed that from the time of intake the period of exposure to retained material will not exceed 50 years.

(b) *Lot Tolerance Percent Defective* means, expressed in percent defective, the poorest quality in an individual inspection lot that should be accepted.

[34 FR 6653, Apr. 18, 1969, as amended at 39 FR 22129, June 20, 1974]

### § 32.3 Maintenance of records.

Each record required by this part must be legible throughout the retention period specified by each Commission regulation. The record may be the original or a reproduced copy of a microform provided that the copy or microform is authenticated by authorized personnel and that the microform is capable of producing a clear copy throughout the required retention period. The record may also be stored in electronic media with the capability for producing legible, accurate, and complete records during the required retention period. Records such as letters, drawings, specifications, must include all pertinent information such as stamps, initials, and signatures. The licensee shall maintain adequate safeguards against tampering with and loss of records.

[53 FR 19246, May 27, 1988]

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### § 32.8 Information collection requirements: OMB approval.

(a) The Nuclear Regulatory Commission has submitted the information collection requirements contained in this part to the Office of Management and Budget (OMB) for approval as required by the Paperwork Reduction Act (44 U.S.C. 3501 et seq.). The NRC may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has approved the information collection requirements contained in this part under control number 3150–0001.

(b) The approved information collection requirements contained in this part appear in §§ 32.11, 32.12, 32.14, 32.15, 32.16, 32.17, 32.18, 32.19, 32.20, 32.21, 32.21a, 32.22, 32.23, 32.25, 32.26, 32.27, 32.29, 32.51, 32.51a, 32.52, 32.53, 32.54, 32.55, 32.56, 32.57, 32.58, 32.61, 32.62, 32.71, 32.72, 32.74, and 32.210.

(c) This part contains information collection requirements in addition to those approved under the control number specified in paragraph (a) of this section. These information collection requirements and the control numbers under which they are approved are as follows:

(1) In § 32.11, NRC Form 313 is approved under control number 3150–0120.

(2) [Reserved]

[49 FR 19625, May 9, 1984, as amended at 59 FR 61780, Dec. 2, 1994; 62 FR 52186, Oct. 6, 1997; 62 FR 63640, Dec. 2, 1997]

## Subpart A—Exempt Concentrations and Items

### § 32.11 Introduction of byproduct material in exempt concentrations into products or materials, and transfer of ownership or possession: Requirements for license.

An application for a specific license on Form NRC-313 authorizing the introduction of byproduct material into a product or material owned by or in the possession of the licensee or another and the transfer of ownership or possession of the product or material containing the byproduct material will be approved if the applicant: